

FINAL ACTION

Applicant's amendment of 1-29-10 has been fully considered. The amended claim 5 has not overcome the previous rejection of 112/2nd paragraph, and applicant's argument has also not overcome the previous 103 rejection based on **Baxter et. al.** (US'005). Thus said rejections are maintained herein.

Claims 1, 2, 8, 9, 12-27, 29, 32, 35, 38, 40-49, 51-83 and 102-105 are cancelled.

Claims 84-98 are withdrawn.

Claims 3-7, 10, 28, 30, 31, 33, 34, 36, 37, 39, 50 and 99-101 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 5 remains rejected under 35 U.S.C. 112, second paragraph, for lacking antecedent basis because claim 5 recites the limitation "*ethyl*" or "*methylamide*" in the majority of the species recited. There is insufficient antecedent basis for this limitation in the claim.

Only the first three species of claim 5 belong to the subgenus of formula III, the rest of the species recited does not fall within the scope of formula III because they have an "*ethyl*" linkage at the 2-position, and a *methylamide* group.

2. Claims 7, 11 and 101 were inadvertently overlooked, but are now rejected under 35 U.S.C. 112, second paragraph, for lacking antecedent basis because claims 7, 11 and 101 recite

the limitation "*ethyl*" or "*methylamide*" in the majority of the species recited. There is insufficient antecedent basis for this limitation in the claim.

In claim 7, the species that do not fall within the scope of formula III are:

- a. the first four species on page 10,
- b. the first 12 species on page 12,
- c. the first, fifth and sixth species on page 13,
- d. the 10th species on page 14,
- e. the fifth thru the 15th species on page 15,
- f. all species on pages 16 & 17,
- g. the first four species on page 18.

All species in claims 11 and 101 do not fall within the scope of formula III.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 3-7, 10, 28, 30, 31, 33, 34, 36, 37, 39, 50 and 99 and 101 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **Baxter et. al.** (US'005 cited previously). The rejection is reiterated herein.

Although claim 3 has been amended to exclude compound #14, the generic teaching of formula II still encompasses the instant formula III when the disclosed formula II (in column 31) has the following substituents:

- i. R_1 is an aryl group;
- ii. R_2 is an alkyl or aryl group;
- iii. L is absent or $-(CH_2)_nNR_2(CH_2)_p-$;
- iv. $n = 0$; $p = 0$;
- v. X is a direct bond;
- vi. Y is $-S(O_2)-$; Z is a direct bond;
- vii. W is substituted or unsubstituted aryl fused to the pyrimidone ring.

Although the reference does not disclose additional species of a sulfonamide substituent at the 2-position, the subgenus formula II in column 31 provides equivalency teaching for one

skilled in the art to select compounds of the instant formula III to agonize or antagonize hedgehog pathway.

As admitted by applicant, the instant formula III is **encompassed** by the reference's formula II. Although no substituent is identified for R₁, R₂ and W, such a detail is not critical because the phenyl groups and R₃ of the instant formula III do not have to be substituted since m, n and t can have a value of 0. Besides, the preferred embodiment on column 32 presents a narrower subgenus that is closer to the instant formula III.

The disclosed formula II compounds are antagonists of hedgehog pathway, and thus, one skilled in the art would have been motivated to select the claimed compounds because such compounds could have had the same antagonistic effect. The reference does not have to disclose the same utility to render obvious structurally similar compounds. Thus, applicant's argument of "No utility or even potential utility was disclosed or suggested for Baxter compounds ... for use as quinazolinone modulators of nuclear receptors in general and (FXR) in particular, ..." is a moot point. See *In re Dillon* 919 F. 2d. 688, 693; 16 USPQ 2d. 1897, 1902 (Fed. Cir. 1990) regarding a prima facie case of obviousness of structurally similar compounds disclosed by a prior art regardless of the properties disclosed in the inventor's application.

Thus, it is maintained that compounds of the instant formula III are obvious over the reference's formula II as pointed out above.

Claim Objections

4. Claim 100 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 100 recites a pharmaceutical composition with an additional antihyperlipidemic agent which is not taught or fairly suggested by the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on Monday thru Friday (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/
Examiner, Art Unit 1624

4-22-10